HERMES DECLARATION EXHIBIT 7 – PART 1 OF 2

BOOK NO. 2175

ETHICON, INC.
a Johnson-Johnson company

Issued to Mark Stickel

Covering the Period

Feb 29, 1988 to

EXHIBIT
D4 121
2/10/06 MM

EXACT COPY

CONFIDENTIAL

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

This notebook is the property of ETHICON INC. and constitutes part of its permanent records.
It should be returned to the company when not in active use, or upon request.

This Page Is Reserved for

TABLE OF CONTENTS

SUBJECT	PAGE
STS PTFE BRAIDS	1
DIE-DRAWING STS BRAIDS	4
IDEA DOUMENTATION — SIMON DE YOUNG BRAIDER	5
IFI CONSTRUCTIONS AND YARN INFO	6
COMPOSITE BRAID EVALUATION	8
MONOFILAMENT / MULTIFILAMENT HYBRID - IDEA DOC.	12
STS - TRIBOHESION PTFE WRAPPED BRAIDS	13
MONOFIL / MULTIFILAMENT HYBRID — FOLLOW-UP IDEA DOC.	15
COMPOSITE BRAIDS - PROCESS + PROPS	16
KAWABATA BENDING TEST - HOT-STRETCH PET	18
BRAID CAD - MODEL CONSTRUCTIONS	19
DUPONT HOLLOW AND MULTILOBAL FIBER	20
POS BRAIDS	22
IFI BRAIDS — PROCESS + PROPS	23
CBE PET/PTFE	26
SURFACE TREATMENT OF VICRYL - IDEA DOC.	31
KAWABATA BENDING - ETH. EXTRA + TICRON	32
VICRYL IMPROVEMENT PROGRAM	33
SILK DEGUMMING + EFFECT ON UNSLEEVING	44
VIP - OESUN σ-ε CURVES	45
KAWABATA - INITIAL + 2ND CYCLE EI FOR VICRYL	47
TEKMAT TREATED VICRYL - HAND PROPS - SURFACE F_2	51
PET MICROFIBER EVALUATION	52
EXPANDED MONOFILAMENT - IDEA DOC	55
PET/PTFE BRAID CONTROL AND PROPS	56
PLIABILIZING PINS IN SUTURE PACKAGE - IDEA DOC.	59
TEKMAT - IN VIVO RESULTS - SURFACE F_2 - VICRYL	60
BCAD - HOT-STRETCH DATA	61
BICOMPONENT PP/PET COMPOSITE BRAID	65

(For Subject Index, see Pages 251 - 258)

Page
Book No. 2175

Project No. 16211 - STS Experiment No. Date 3/31/88

Subject STS - PTFE BRAIDS - REPLICATION OF A. HUNTER'S STS CONSTRUCTIONS

Purpose TO VERIFY THE MANUFACTURING CONDITIONS FOR THREE STS BRAID CONSTRUCTIONS (SIZE 2/0, 0, 2) WHICH WERE DEVELOPED BY A. HUNTER.

NOTEBOOK #	2175-1A	2175-1B	2175-1C
EXPERIM. # (D. REMBERT)	STZ-001	STZ-002	STZ-003
START DATE	3/28/88	3/28/88	3/28/88
BRAIDER #	1	00	3
SIZE	2	0	2-0
YN COLOR/DEX	PTFE/WHITE	PTFE/WHITE	PTFE/WHITE
CONSTRUCTION	16x3	12x1	8x1
PICK GEAR	40	31	42
BRAIDER RPM	100	~~100~~ (9 YDS/HR)	~~100~~ 9 YDS/HR
SHEATH LOT #	225-30-0-TI143	225-30-0 TI143	225-30-0 TI143
SHEATH CONSTRUC.	1/6 225 DEN	225 DEN x 1/0	225 DEN x 1/0
SHEATH DESCRIP	PTFE MULTIFIL DUPONT	PTFE MULTI (DUPONT)	PTFE MULTIF. (DUPONT)
CORE DESCRIP	PTFE MULTIF. (DUPONT)	PTFE MULTI (DUPONT)	PTFE MULTIF. (DUPONT)
CORE LOT #	225-30-0 TI143	225-30-0 TI143	225-30-0 TI143
CORE CONSTRUC.	1/3 450 DEN	1/0 225 DEN	225 DEN x 1/0
SHEATH TENSION SPNG	0.011 x 5½ GRN	0.009 x 5" NAT	0.009 x 5" NAT
CORE TENS SPRING	0.011 x 5½ GRN	0.009 x 5" NAT	0.009 x 5" NAT
TEN DEN (CORE)	BUTT CARRIER	BUTT CARRIER	BUTT CARRIER
QUANTITY	480 YDS	500 YDS	760 YDS

COMMENTS:

2175-1A: RANDOM MODULAR GEOMETRY VISABLE WITH NAKED EYE AT 3-5 CM INTERVALS APPARENTLY DUE TO "CORE-POPPING" (CORE CAN BE PULLED OUT THRU SHEATH WALL AT NODE).

MICRO EVAL (25X): A GREAT DEAL OF ENTRAPPED BLACK CONTAMINENT & V. FEW LITTLE BROKEN FILAMENTS

Investigator [signature] Date 4/14/88

Witness Crawford Britt Date 3-15-90

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002607

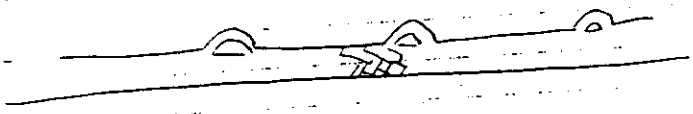
Project No. CONT. FROM PREVIOUS PAGE Experiment No. Date

Subject

Purpose

2175

2175-1B : VISUAL BUMPY SURFACE. MICRO EVAL (25X) - ONE CARRIER IS CONSISTENTLY BUCKLED OUT OF BRAID STRUCTURE.



2175-1C : VISUAL - SLIGHTLY IRREGULAR SURFACE. MICRO EVAL (25X) - BRAID SOME WHAT LOOSE - ESPECIALLY ONE OR TWO CARRIERS WHICH OCCASIONALLY SLIGHTLY BUCKLE OUT OF PLANE. BRAID APPEARS FACETED DUE TO 8 CARRIER CONSTRUCTION. ORTH. DIAM: 17.0 MIL

GENERAL OVERALL COMMENTS : BRAID PROCESS CONDITIONS REQUIRE OPTIMIZATION.

MS

31 | 45

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002608

Investigator [signature] Date 3/16/90

Witness Ronald Britt Date 3-15-90

Page
Book No. 2175

Project No. 16211-STS Experiment No. Date 3/31/88

Subject PROCESS CHANGES FOR STS BRAIDS

Purpose TO OBTAIN HIGHER QUALITY BRAID STOCK FOR STS SIZES 2, 2/0, AND 0 BY ADJUSTING CARRIER TENSIONS ON BRAIDER. PREVIOUS PROCESS CONDITIONS REPORTED BY A. HUNTER RESULTED IN CORE-POPPING AND OTHER BRAID DEFECTS (2175-1A, 1B, 1C).

NOTE: ALL BRAID PROCESS CONDITIONS SAME AS 2175-1A, 1B AND 1C EXCEPT FOR:

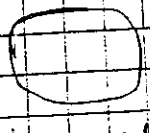
NOTEBOOK #	2175-3A	2175-3B	2175-3C
EXPER #	STZ-004	STZ-005	STS-006
START DATE	3/31/88	3/31/88	3/31/88
SHEATH TENSION SPRING	0.011 x 5½ GN	0.009 x 5 NAT	009 x 5" NAT
CORE TENSION SPRING	0.012 x 5½ OR	.011 x 5½ GN	011 x 5½ GN
OTHER CHANGES		ONE CARRIER REMOVED AND CLEANED (TENSION MECH STICKING), CHANGE ALL SPRINGS, 3 BOBBINS CHANGED	NEW SPRINGS, CHANGE 4 CARRIERS, CLEAN BRAIDER

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

COMMENTS:

2175-3A: HIGHER CORE TENSION ELIMINATED CORE-POPPING OBSERVED IN 2175-1A. GOOD QUALITY (25X), GOOD CIRCULAR GEOM. SOME TRASH. OPTICAL DIAM = 27.1 mil.

2175-3B: GOOD QUALITY, SMOOTH. MICRO EVAL (25X): SOME OCCASIONAL LOOSENESS AND BROKEN FILAMENTS. BRAID SOMEWHAT RECTANGULAR IN X-SECT. IMPROVEMENTS PROBABLY DUE TO CARRIER CHANGES + CLEANING



2175-3C: IRREG SMOOTHNESS. GOOD QUALITY BUT SQUARISH X-SECT DUE TO PACKING CHAR OF 8 CARRIER CONSTRUCTIONS WITH THIS YARN. OPTICAL DIAM = 17.6 mils

Investigator [signature] Date 3/31/88

Witness Crawford Britt Date 3-15-90

Page
Book No.
2173

Project No. 6211-STS Experiment No. Date 4/15/88
Subject DIE-DRAWING TRIALS OF STS PTFE BRAIDS / INCOMING YARN VARIABILITY
Purpose:

PROCEDURE: DIE-DRAWING OF PTFE BRAIDS PERFORMED PER AL HUNTER'S "PROCESS TRANSFER MEMO OF STS SUTURES" OF 10/29/87, SUCH AS (1) BRAID WAS DRAWN THRU STEEL WIRE DIES, (2) BRAID WAS SIMULTANEOUSLY BEING HOT-STRETCHED USING GODET SET-UP AND A FORCED CONVECTION TUNNEL OVEN AT 315°F, AND (3) MULTIPLE PASSES WITH DECREASING DIE SIZE.

RESULTS

- DIE-DRAWING SIGNIFICANTLY REDUCES THE BRAID PROFILE OF THE PTFE BRAIDS IN ALL CASES IN THE "UNPERTURBED" OR RELAXED CONDITION. HOWEVER, A LOW AMOUNT OF TORSION OR EVEN BENDING OF THE SUTURE TYPICAL OF THE MANIPULATION REQUIRED FOR KNOT TIE-DOWN RESULTS IN A DRASTIC OPENING UP OF THE BRAID STRUCTURE. THUS, THE BRAID STRUCTURE IS APPARENT IN USE ALTHOUGH IT APPEARS 'MONOFILAMENT-LIKE' IN THE RELAXED CONDITION.

- PRODUCT UNIFORMITY (DIAMETER) IS CRITICAL IN THE DIE-DRAWING OPERATION WITH THE RISKS OF FREQUENT LINE BREAKAGE ~~AND~~ (ENLARGED ~~LARGE~~ REGIONS) AND ROUGH (UNDERSIZED REGIONS) FOR VARIABLE MATERIAL. THIS MOST LIKELY RESULTS FROM THE APPARENT LARGE VARIATIONS IN YARN DENIER (AND DIAMETER) OF THE DUPONT TEFLON YARN. TYPICAL DEVIATIONS WERE:

DUPONT LABELED DEN	ETHICON MEAS. DEN
66	88
64	83
84	102

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002610

Investigator [signature] Date 4/15/88
Witness [illegible] Date 3-15-90

Page
Book No. 2175

Project No. BRAID EQUIP Experiment No. IDEA Date 4/18/88
Subject NOVEL BRAIDING EQUIPMENT FOR SUTURE MANUFACTURE
Purpose DOCUMENT CONCEPTS RELATING TO SIMON DEYOUNG M/C

IDEA: SIGNIFKANT IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY BE ACHIEVED BY UTILIZING A NOVEL BRAID MECHANISM OFFERED SIMON DE YOUNG CO. THE MECHANISM IS BASED ON THE FOLLOWING FEATURES: (1) CARRIERS RESIDE ON TWO HORIZONTAL PLANES VS. ONE FOR CONVENTIONAL BRAIDERS, (2) CARRIERS MOVE IN CIRCULAR PATH VS. SERPENTINE PATH FOR CONVENTIONAL BRAIDERS, AND (3) INTERLACING OCCURS BY DIVERSION OF STRAND PATH OF LOWER PLANE OF CARRIERS BY A MOVING YARN GUIDE.

IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY INCLUDE:

1) LONGER PROCESS RUNS — CARRIER PACKAGE DIAMETER IS INCREASED SINCE CARRIERS RESIDE ON 2 PLANES WHICH ALLOWS MORE YARN / BOBBIN. LARGER BOBBINS → MORE ECONOMICAL SINCE LESS SET-UP TIME

2) HIGHER BRAIDER SPEEDS — DUE TO CIRCULAR CARRIER PATH VS SERPENTINE. MORE ECONOMICAL + SHORTER EXPOSURE TIMES FOR ABSORBABLE MATERIALS.

3) IMPROVEMENT IN BRAID UNIFORMITY — MORE CONSTANT YARN TENSION DURING BRAIDING SINCE DISTANCE FROM BOBBIN TO BRAIDING PT REMAINS CONSTANT THROUGHOUT REVOLUTION (VS SERPENTINE PATH + FLUCTUATING TENSION) TRANSLATES TO IMPROVED SMOOTHNESS + HAND

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002611

Investigator [signature] Date 4/18/88
Witness Crawford Britt Date 3-15-90

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

Book No. 2175

Project No. IFI Experiment No. Date 5/12/88

Subject DEFINE CONSTRUCTIONS AND YARN INFO FOR IFI BRAIDS

Purpose IFI CONSTRUCTIONS + YARN INFO

BACKGROUND: A CONCEPT WAS FOWARDED BY DR. E. BROYER + SUTURE DEVELOPMENT TO PRODUCE A MONOFILAMENT LIKE SUTURE BY BRAIDING 2 DIFFERENT POLYMER FIBER TYPES WITH A DIFFERENTIAL IN T_m AND SUBSEQUENTLY MELTING THE LOWER T_m FIBER TO FORM A MATRIX AROUND THE HIGHER T_m FIBER REINFORCEMENT. WORK IS TO BE PERFORMED IN CONJUNCTION WITH THE ISRAELI FIBER INSTITUTE (IFI)

PURPOSE: DEFINE BRAID CONSTRUCTIONS AND DOCUMENT YARN LOT INFO FOR IFI BRAIDS

TWO TYPES OF BRAID COMPOSITES ARE SUGGESTED BY DR. BROYER: 1) ROOT BRAIDS — CORE + SHEATH ARE DIFFERENT FIBERS AND 2) RMF OR "REINFORCED MONOFILAMENT" WHERE THE 2 FIBERS ARE BLENDED IN THE CORE + SHEATH.

EARLIER IFI BRAID CONSTRUCTIONS TO BE PROCESSED INCLUDE:

IFI BRAID CONSTRUCTIONS

IFI-	FIBER 1 TYPE	FIBER 2 TYPE	SHEATH X CORE CARRIERS	SHEATH FIB 1 DENIER	SHEATH FIB 2 DENIER	CORE FIB 1 DENIER	CORE FIB 2 DENIER
1	VIC	PDS	8X3	28	*	*	60
2	VIC	PDS	4X5	52	*	*	48
3	PET	PP	4X3	40	*	*	86
4	VIC	PDS	8X3	56	*	*	60
5	VIC	PDS	12X5	28	*	*	60
6	PET	PP	8X3	40	*	*	100
7	PET	PP	8X3	30	20	70	*
8	PET	PP	12X3	20	20	55	*
9	VIC	PDS	8X1	52	24	*	60
10	PET	PP	8X3	20	20	55	60
11	VIC	PDS	12X1	28	24	*	60
12	VIC	PDS	8X1	28	48	52	*
13	PET	PP	8X3	20	20	*	100
14	VIC	PDS	12X3	14	24	14	48
15	PET	PP	8X3	20	*	*	86

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002612

MS 5/12/88

Investigator [signature] Date 5/12/88

Witness [illegible] Date 3-15-90

Vol. ....
No. ....
2175

Project No. 16211-STS Experiment No. .... Date 4/15/88
Subject DIE-DRAWING TRIALS OF STS PTFE BRAIDS / INCOMING YARN VARIABILITY
Purpose :

PROCEDURE: DIE-DRAWING OF PTFE BRAIDS PERFORMED PER AL HUNTER'S "PROCESS TRANSFER MEMO OF STS SUTURES OF 10/29/87, SUCH AS (1) BRAID WAS DRAWN THRU STEEL WIRE DIES, (2) BRAID WAS SIMULTANEOUSLY BEING HOT-STRETCHED USING GODET SET-UP AND A FORCED CONVECTION TUNNEL OVEN AT 315°F, AND (3) MULTIPLE PASSES WITH DECREASING DIE SIZE.

RESULTS

- DIE-DRAWING SIGNIFICANTLY REDUCES THE BRAID PROFILE OF THE PTFE BRAIDS IN ALL CASES IN THE "UNPERTURBED" OR RELAXED CONDITION. HOWEVER, A LOW AMOUNT OF TORSION OR EVEN BENDING OF THE SUTURE TYPICAL OF THE MANIPULATION REQUIRED FOR KNOT TIE-DOWN RESULTS IN A DRASTIC OPENING UP OF THE BRAID STRUCTURE. THUS, THE BRAID STRUCTURE IS APPARENT IN USE ALTHOUGH IT APPEARS 'MONOFILAMENT-LIKE' IN THE RELAXED CONDITION.

- PRODUCT UNIFORMITY (DIAMETER) IS CRITICAL IN THE DIE-DRAWING OPERATION WITH THE RISKS OF FREQUENT LINE BREAKAGE (OVERSIZED REGIONS) AND ROUGH (UNDERSIZED REGIONS) FOR VARIABLE MATERIAL. THIS MOST LIKELY RESULTS FROM THE APPARENT LARGE VARIATIONS IN YARN DENIER (AND DIAMETER) OF THE DUPONT TEFLON YARN. TYPICAL DEVIATIONS WERE:

DUPONT LABELED DEN	ETHICON MEAS. DEN
66	88
64	83
88	102

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002613

Investigator [signature] Date 4/15/88
Witness [signature] Date 3-15-90

Page
Book No. 2175

Project No. BRAID EQUIP Experiment No. IDEA Date 4/18/88
Subject NOVEL BRAIDING EQUIPMENT FOR SUTURE MANUFACTURE
Purpose DOCUMENT CONCEPTS RELATING TO SIMON DEYOUNG M/C

IDEA: SIGNIFICANT IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY BE ACHIEVED BY UTILIZING A NOVEL BRAID MECHANISM OFFERED SIMON DE YOUNG CO. THE MECHANISM IS BASED ON THE FOLLOWING FEATURES: (1) CARRIERS RESIDE ON TWO HORIZONTAL PLANES VS. ONE FOR CONVENTIONAL BRAIDERS, (2) CARRIERS MOVE IN CIRCULAR PATH VS. SERPENTINE PATH FOR CONVENTIONAL BRAIDERS, AND (3) INTERLACING OCCURS BY DIVERSION OF STRAND PATH OF LOWER PLANE OF CARRIERS BY A MOVING YARN GUIDE.

IMPROVEMENTS IN SUTURE BRAID PROCESSING MAY INCLUDE:

1) LONGER PROCESS RUNS — CARRIER PACKAGE DIAMETER IS INCREASED SINCE CARRIERS RESIDE ON 2 PLANES WHICH ALLOWS MORE YARN / BOBBIN. LARGER BOBBINS → MORE ECONOMICAL SINCE LESS SET-UP TIME

2) HIGHER BRAIDER SPEEDS — DUE TO CIRCULAR CARRIER PATH VS SERPENTINE. MORE ECONOMICAL + SHORTER EXPOSURE TIMES FOR ABSORBABLE MATERIALS.

3) IMPROVEMENT IN BRAID UNIFORMITY — MORE CONSTANT YARN TENSION DURING BRAIDING SINCE DISTANCE FROM BOBBIN TO BRAIDING PT REMAINS CONSTANT THROUGHOUT REVOLUTION (VS SERPENTINE PATH + FLUCTUATING TENSION). TRANSLATES TO IMPROVED SMOOTHNESS + HAND

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002614

Investigator [signature] Date 4/18/88
Witness Crawford Britt Date 3-15-90

ge
No. 175

Project No. IFI Experiment No. Date 5/12/88

Subject DEFINE CONSTRUCTIONS AND YARN INFO FOR IFI BRAIDS

Purpose IFI CONSTRUCTIONS + YARN INFO

BACKGROUND: A CONCEPT WAS FOWARDED BY DR. E. BROYER + SUTURE DEVELOPMENT TO PRODUCE A MONOFILAMENT LIKE SUTURE BY BRAIDING 2 DIFFERENT POLYMER FIBER TYPES WITH A DIFFERENTIAL IN T_M AND SUBSEQUENTLY MELTING THE LOWER T_M FIBER TO FORM A MATRIX AROUND THE HIGHER T_M FIBER REINFORCEMENT. WORK IS TO BE PERFORMED IN CONJUNCTION WITH THE ISRAELI FIBER INSTITUTE (IFI)

PURPOSE: DEFINE BRAID CONSTRUCTIONS AND DOCUMENT YARN LOT INFO FOR IFI BRAIDS.

TWO TYPES OF BRAID COMPOSITES ARE SUGGESTED BY DR. BROYER: 1) ROOT BRAIDS — CORE + SHEATH ARE DIFFERENT FIBERS AND 2) RMF OR "REINFORCED MONOFILAMENT" WHERE THE 2 FIBERS ARE CARRIED BLENDED IN THE CORE + SHEATH.

IFI BRAID CONSTRUCTIONS TO BE PROCESSED INCLUDE:

IFI BRAID CONSTRUCTIONS

IFI-	FIBER 1 TYPE	FIBER 2 TYPE	SHEATH X CORE CARRIERS	SHEATH FIB 1 DENIER	SHEATH FIB 2 DENIER	CORE FIB 1 DENIER	CORE FIB 2 DENIER
1	VIC	PDS	8X3	28	*	*	60
2	VIC	PDS	4X5	52	*	*	48
3	PET	PP	4X3	40	*	*	86
4	VIC	PDS	8X3	56	*	*	60
5	VIC	PDS	12X5	28	*	*	60
6	PET	PP	8X3	40	*	*	100
7	PET	PP	8X3	30	20	70	*
8	PET	PP	12X3	20	20	55	*
9	VIC	PDS	8X1	52	24	*	60
10	PET	PP	8X3	20	20	55	60
11	VIC	PDS	12X1	28	24	*	60
12	VIC	PDS	8X1	28	48	52	*
13	PET	PP	8X3	20	20	*	100
14	VIC	PDS	12X3	14	24	14	48
15	PET	PP	8X3	20	*	*	86

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002615

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

MS 5/12/88

Investigator

Date 5/12/88

Witness

Date 2-15-90

Page 6
Book No. 2175

Project No. IFI Experiment No. Date 5/12/88
Subject IFI BRAID CONSTRUCT + YARN LOT ID
Purpose

IFI - CONT FROM PG. 6

VICRYL/PDS AND PET/PP COMPOSITES ARE TO BE PROCESSED FROM THE FOLLOWING YN. LOTS:

IFI YARN LOT INFORMATION

IFI #	FIBER 1	FIBER 2	SHEATH FIB 1 DENIER	SHEATH FIB 1 LOT #	SHEATH FIB 2 DENIER	SHEATH FIB 2 LOT #	CORE FIB 1 DENIER	CORE FIB 1 LOT #	CORE FIB 2 DENIER	CORE FIB 2 LOT #
1	VIC	PDS	28	XC3374	*	*	*	*	60	PY-010 60/10
2	VIC	PDS	52	XC3349	*	*	*	*	48	PY-001.3-48/4
3	PET	PP	40	40/27-R14-56	*	*	*	*	86	PP-001-5 5DPF
4	VIC	PDS	56	XC-3371	*	*	*	*	60	RLS-248B-60/5
5	VIC	PDS	28	XC-3181	*	*	*	*	60	RLS-248B-60/5
6	PET	PP	40	40/27-R14-56	*	*	*	*	100	PP002-1
7	PET	PP	30	30-20-R14-56	20	21.4-PP-005	70	70-34-R14-55	*	*
8	PET	PP	20	20-10-RXX-56	20	20.7-PP-004	55	55-27-R02-52	*	*
9	VIC	PDS	52	52-26-C3388	24	24-2-PY-003	*	*	60	60-10-PY-010
10	PET	PP	20	20-10-R02-56	20	PP-004	55	55-27-R02-52	60	PP-003
11	VIC	PDS	28	XC3374	24	PY-37-2-0	*	*	60	PY-010
12	VIC	PDS	28		48		52		*	*
13	PET	PP	20	20-10-R02-56	20	*	*	PP-004	100	PP-003
14	VIC	PDS	14	*	24	*	14	*	48	*
15	PET	PP	20	20-10-R02-56	*	*	*	*	86	PP-001

MS 5/12/88

BRAID PROCESS CONDITIONS, HOT-STRETCH PARAMETERS AND PROPERTIES OF THE IFI BRAIDS WILL BE SUMMARIZED AT A FUTURE DATE.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002616

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

Investigator [signature] Date 5/12/88
Witness [illegible] Date 2-15-90

(CBE)

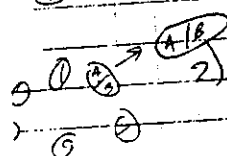
Project No. COMPOSITE BRAIDS Experiment No. _____ Date 6/6/88

Subject COMPOSITE BRAID EVAL - BRAID CONSTRUCTIONS, YARN LOT, IN PROCESS

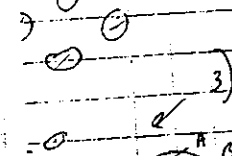
Purpose

BACKGROUND: A PRELIMINARY EVALUATION OF COMPOSITE BRAIDS, i.e. BRAIDED SUTURES CONSTRUCTED OF TWO OR MORE FIBER TYPES DESIGNED TO REALIZE THE BENEFICIAL PROPERTIES OF EACH POLYMER. COMPOSITES TO BE EVALUATED INCLUDE PET/PTFE, PET/PP AND (ABSORBABLE) PDS / ULTRA. FOUR PROCESS METHODOLOGIES WILL BE EMPLOYED TO COMBINE THE DIFFERENT FIBER TYPES INTO COMPOSITE BRAIDS:

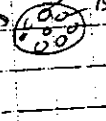
1) CARRIER BLENDING: BLENDING IS ACCOMPLISHED DURING BRAIDING BY DIVIDING THE CARRIERS INTO TWO SETS WITH YARN A RESIDING ON ONE SET AND YARN B ON THE OTHER.



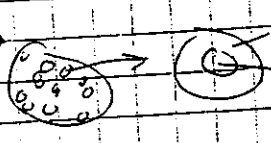
2) YARN BLENDING: BLENDING IS ACCOMPLISHED PRIOR TO BRAIDING BY PLYING YARNS A + B TOGETHER AND TO FORM A COMPOSITE YARN.



3) FIBER COMMINGLING - BLENDING IS ACCOMPLISHED ON FIBER LEVEL BY THE 'COMMINGLING PROCESS' (CONCORDIA, RI) IN WHICH FIBERS A + B ARE INTIMATELY INTERMINGLED MOST LIKELY BY AIR-JET



4) BICOMPONENT FIBERS: BLENDING IS ACCOMPLISHED ON THE FIBER LEVEL BY EXTRUSION OF TWO POLYMERS (CONCENTRIC) PER FILAMENT.



THE LEVEL OF BLEND HOMOGENEITY INCREASES FROM 1 → 4.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

Investigator _____ Date 6/6/88

Witness _____ Date 2-15-90

DePuy Mitek, Inc. v. Arthrex, Inc. C.A. No. 04-12457 PBS DMI002617

Book No. 2175

Project No. CBE Experiment No. Date 6/6/88

Subject CONTINUED

Purpose

THE INITIAL COMPOSITE BRAID EVALUATION WILL FOCUS ON 15 CONSTRUCTIONS OF PET/PTFE, VICRYL/PDS + PET/PP BLENDS:

COMPOSITE BRAID EVALUATION
BRAID CONSTRUCTIONS

MGS ID#	COMP TYPE	BRAID TYPE	SIZE	SHxCR CARR.	FIBER A	DEN A	FIBER A VOLUM FRACT	FIBER B	DEN B	FIBER B VOLUM FRACT	FIBER C	DEN C	FIBER C VOLUM FRACT	SH CARR FIB A	SH CARR FIB B	CR CARR FIB A	CR CARR FIB
CBE-01	CB	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-7\0	2-8\E	1-3	1-3
CBE-02	YB	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-8	1-8	1-3	1-3
CBE-03	CF	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-8	1-8	1-3	1-3
CBE-04	CT	CS	X-0	8x3	PET	70		PTFE	75		*	*		1-8	*	1-3	*
CBE-05	CT	CS	X-0	8x3	PET	70		PTFE	75		*	*		*	1-8	*	1-3
CBE-06	CB	CS	2-0	12x1	VICRYL	28	34	PDS	48	66	*	*	*	1-11\0	2-12\E	1	1
CBE-07	YB	CS	2-0	12x1	VICRYL	28	34	PDS	48	66	*	*	*	1-12	1-12	1	1
CBE-08	CF	CS	2-0	12x1	VICRYL	28	34	PDS	48	66	*	*	*	1-12	1-12	1	1
CBE-08A	CF	CS	X-0	12x1	VICRYL	28		PDS	48		*	*		1-12	1-12	1	1
CBE-09	CT	CS	2-0	12x1	VICRYL	28	100	PDS	48	0	*	*	*	1-12	*	1	*
CBE-10	CT	CS	2-0	12x1	VICRYL	28	0	PDS	48	100	*	*	*	*	1-12	*	1
CBE-11	CF	CS	X-0	12x1	PET	70		PP	50		*	*		1-12	1-12	1	1
CBE-12	BF	CS	X-0	12X1	PET/PP	60		*	*		*	*		1-12	*	1	*
CBE-13	CT	CS	X-0	12X1	PET	70		PP	50		*	*		1-12	*	1	*
CBE-14	CT	CS	X-0	12X1	PET	70		PP	50		*	*		*	1-12	*	1
CBE-15	CB	CS	1	12x1	PET	70	51	PTFE	110	49	*	*	*				

MS 6/6/88

MS 6/6/88

KEY:

CB : CARRIER BLEND
YB : YARN BLEND
CF : COMMINGLED FIBER
BF : BICOMPONENT FIBER
CT : CONTROL

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002618

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

Investigator [signature] Date 6/6/88

Witness [illegible] Date 2-15-91

Page
No. 175

Project No. CBE Experiment No. Date 6/6/88

Subject CONT

Purpose

YARN LOT INFORMATION FOR CBE 1-15 :

COMPOSITE BRAID EVALUATION
YARN A DESCRIPTION

MGS ID#	FIBER A	FIB A DENIER	FIB A FILAM COUNT	FIB A SOURCE	FIB A LOT #	FIB A COLOR	FIB A TWIST LEVEL (TPI)	FIB A TWIST DIRCT (S/Z)	FIB A ENTANG LEVEL
CBE-01	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-02	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		*
CBE-03	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		*
CBE-04	PET	70	48	SUT DEV	SPX-305	GREN	0.0 *		*
CBE-05	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-06	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0 *		0
CBE-07	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0 *		0
CBE-08	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0 *		0
CBE-08A	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0 *		0
CBE-09	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0 *		0
CBE-10	VICRYL	28	14	CORNELIA	ZC3606	NATR	0.0 *		0
CBE-11	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-12	PET/PP	60	0	BASF		WHIT	0.0 *		0
CBE-13	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-14	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-15	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0

COMPOSITE BRAID EVALUATION
YARN B DESCRIPTION

MGS ID#	FIBER B	FIB B DENIER	FIB B FILAM COUNT	FIB B SOURCE	FIB B LOT #	FIB B COLOR	FIB B TWIST LEVEL (TPI)	FIB B TWIST DIRCT (S/Z)	FIB B ENTNG LEVEL
CBE-01	PTFE	75	12	DUPONT	1T153	WHIT	0.0 *		LOW
CBE-02	PTFE	75	12	DUPONT	1T153	WHIT	0.0 *		*
CBE-03	PTFE	75	12	DUPONT	1T153	WHIT	0.0 *		LOW
CBE-04	PTFE	75	12	DUPONT	1T153	WHIT	0.0 *		LOW
CBE-05	PTFE	75	12	DUPONT	1T153	WHIT	0.0 *		LOW
CBE-06	PDS	48	4	SUT DEV	PY001	PURP	0.0 *		0
CBE-07	PDS	48	4	SUT DEV	PY001	PURP	0.0 *		0
CBE-08	PDS	48	8	SUT DEV	PY035	PURP	0.0 *		0
CBE-08A	PDS	48	4	SUT DEV	PY001	PURP	0.0 *		0
CBE-09	PDS	48	4	SUT DEV	PY001	PURP	0.0 *		0
CBE-10	PDS	48	4	SUT DEV	PY001	PURP	0.0 *		0
CBE-11	PP	50	16	SUT DEV	PP005	WHIT	0.0 *		0
CBE-12	*	*	0	*	*	*	0.0 *		0
CBE-13	PP	50	16	SUT DEV	PP005	WHIT	0.0 *		0
CBE-14	PP	50	16	SUT DEV	PP005	WHIT	0.0 *		0
CBE-15	PTFE	110	15	DUPONT	1T138	WHIT	0.0 *		0

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002619

Investigator [signature] Date 6/6/88

Witness [signature] Date 3-15-90

Page 11

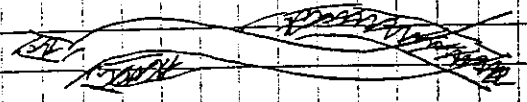
Book No. 2175

Project No. CBE Experiment No. Date

Subject CONTINUED

Purpose

THE YARN BLEND COMPOSITES REQUIRE A PLYING/TWISTING OPERATION BEFORE BRAIDING. PLYING WAS PERFORMED ON THE RATTI 2-FOR-1 TWISTER UTILIZING THE CONDITIONS LISTED IN THE TABLE. PROPER BALANCING OF YARN TENSION WERE REQUIRED TO PREVENT A BARBER POLE APPEARANCE:



PROPER BALANCE OF TENSION

BARBER-POLE APPEARANCE - DUE TO MIS-MATCH IN YARN ELASTIC MODULUS AND TENSION LEVELS

COMPOSITE BRAID EVALUATION
PLIED YARN PROCESS CONDITIONS

MGS ID#	FIBER A	DENIER A	FIBER B	DENIER B	PLY TWIST LEVEL (TPM)	CAN YARN	CREEL YARN	CAN YARN # BRASS DISC WTS	CREEL YARN # GLASS BEADS
CBE-01	PET	70	PTFE	75	0.0	*	*	0	0
CBE-02	PET	70	PTFE	75	3.0	B	A	0	1
CBE-03	PET	70	PTFE	75	0.0	*	*	0	0
CBE-04	PET	70	PTFE	75	0.0	*	*	0	0
CBE-05	PET	70	PTFE	75	0.0	*	*	0	0
CBE-06	VICRYL	28	PDS	48	0.0	*	*	0	0
CBE-07	VICRYL	28	PDS	48	3.0	B	A	0	1
CBE-08	VICRYL	28	PDS	48	0.0			0	0
CBE-08A	VICRYL	28	PDS	48	0.0			0	0
CBE-09	VICRYL	28	PDS	48	0.0	*	*	0	0
CBE-10	VICRYL	28	PDS	48	0.0	*	*	0	0
CBE-11	PET	70	PP	50	0.0			0	0
CBE-12	PET/PP	60	*	*	0.0			0	0
CBE-13	PET	70	PP	50	0.0			0	0
CBE-14	PET	70	PP	50	0.0			0	0
CBE-15	PET	70	PTFE	110	0.0	*	*	0	0

MS 6/6/88

Investigator

Date 6/6/88

Witness Crawford Britt

Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI002620

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

Page 10
Book No. 2175

Project No. MICROFIBER / MMF Experiment No. Date 8/18/88
Subject MONOFILAMENT - / MULTIFILAMENT HYBRID WITH MICROFIBER CORE
Purpose IDEA

IDEA: A IMPROVED SUTURE IS ENVISIONED WHICH COMBINES THE ATTRIBUTES OF MONOFILAMENTS (EASE OF TISSUE PASSAGE, NO INFECTION HARBORING INTERSTICES) AND THE ATTRIBUTES OF MULTIFILAMENT BRAIDS (PLIABILITY, KNOT STR., KNOT STABILITY, DAMAGE TOLERANCE). THE HYBRID DESIGN CONSISTS OF POTENTIALLY FOUR COMPONENTS: 1) MONOFILAMENT-LIKE SHEATH, 2) CORE MULTIFILAMENT BUNDLE, 3) SHEATH-CORE INTERFACE, AND 4) MULTIFILAMENT CORE LUBRICANT (OPTIONAL). MONOFIL SHEATH IS PREFERABLY FORMED BY EXTRUSION ON CABLE-WRAPPING / POLISHING. SHEATH POLYMER CAN BE ABSORBABLE OR NONABSORBABLE, AND SHOULD BE TOUGH, LOW MODULUS, & POSESS THE PROPER FRICTIONAL PROPERTIES.

MULTIFILAMENT CORE CONSISTS OF A BUNDLE OF MANY FINE FILAMENTS (1.0 DAF AND FINER) WHICH MAY BE TWISTED OR BRAIDED. TWISTED STRUCTURES SHOULD BEHAVE WITH ENHANCED PLIABILITY, WHEREAS BRAIDED STRUCTURES SHOULD MAINTAIN ROUNDNESS BETTER.

TWO APPROACHES ARE POSSIBLE REGARDING THE SHEATH-CORE INTERFACE. ONE IS TO MAXIMIZE ADHESION TO PREVENT TEARING / STRIPPING. IT IS BELIEVED THAT THIS WILL DETRACT FROM PLIABILITY BY INHIBITING YARN/FIBER MOBILITY. THE OTHER APPROACH IS TO MINIMIZE SHEATH-CORE ADHESION, POSSIBLY BY THE INCORPORATION OF AN OIL LIKE LUBRICANT (SILICONE OIL FOR EXAMPLE) OR SOLID LUBRICANT LIKE PTFE FIBERS IN THE CORE BUNDLE. THIS SAME LUBRICATION APPROACH MAY BE OF VALUE WITHIN THE CORE BUNDLE TO MINIMIZE FIBER-FIBER INTERACTIONS.

THE RESULTING SUTURE SHOULD HAVE EXC. TISSUE PASSAGE, PLIABILITY, KNOT PULL, RESISTANCE TO CATASTROPHIC DAMAGE AND MINIMAL TENDENCY FOR INFECTION HARBORING.

Investigator [signature] Date 8/18/88
Witness [illegible] Date 3-15-90

Book No. 2175

Project No. STS Experiment No. Date 9/27/88

Subject TRIBOHESION PROCESSED STS BRAID SAMPLES

Purpose SEM + PHYS. PROP CHARACTERIZATION

BACKGROUND: 23 SAMPLES OF TRIBOHESION (LONDON, UK) PROCESSED BRAID SAMPLES WERE SUPPLIED BY MR E. NAGY IN OUR MEETING AT ETHICON ON 7/26/88. THE STRANDS WERE COMPRISED OF 2-0 STS PTFE BRAID WHICH WAS CABLE WRAPPED AND POLISHED. STRAND LENGTH WAS 1-2 M. LIMITED INFORMATION WAS RELEASED BY TRIBOHESION ON THE PROCESSING OF THE SAMPLES, BUT IT IS KNOWN THAT THE PROCESS VARIABLES INCLUDE LINE SPEED, TAPE TENSION, TAPE WIDTH + THICKNESS, AND DEGREE OF POLISHING.

RESULTS: PHYSICAL PROPERTY CHARACTERIZATION VS. ORIGINAL STS BRAID AND GORE-TEX:

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

PHYSICAL PROPERTY CHARACTERIZATION

PROPERTY	UNITS	ORIGINAL 2-0 STS BRAID	TRIBOHESION PROCESSED 2-0 STS BRAID #13	GORE-TEX SIZE 4-0 MONOFILAM.
DIAMETER	(MILS)	12.1	20.2	13.6
USP	(MILS)	N/A	26.5	N/A
OPTICAL				5.0
STR. TENSILE	(LBS)	4.1	7.8	
INTRIN. TENSILE (USP DIAM)	(PSI)	35,600	24,300	34,400
ULT. ELONGATION	(%)	20.0	55.1	25.5
KNOT STRENGTH	(LBS)	3.9	7.1	4.1
INTRIN. KNOT	(PSI)	33,900	22,100	28,200
KNOT/STRAIGHT STR	(%)	95	91	82
KNOT SECURITY *	(# OF THROWS)	6	5-6	6-7

N/A : not available

* : composite of several lots and sizes

9/27/88

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002622

Investigator [signature] Date 9/27/88

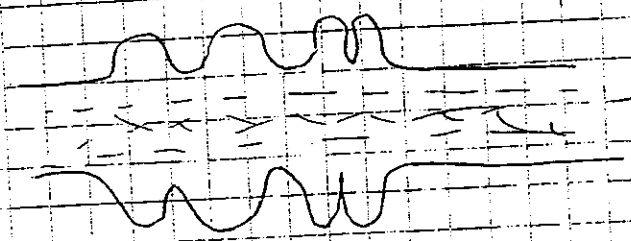
Witness [illegible] SMITH Date 2-15-97

Page
Book No.
2175

Project No. Experiment No. Date 9/27/88
Subject TRIBOHESION
Purpose CONTINUED

SEM OBSERVATIONS:

1) SAMPLES WITH POOR SUBJECTIVE SMOOTHNESS POSSESSED AN OVERSIZED SHEATH WHICH DISTORTED EASILY. DISTORTION WAS EITHER A WRINKLING DUE TO TORSION OR AN BELLOWS TYPE FOLDING DUE TO SHEATH SLIDING.



BELLOWS TYPE SHEATH FOLDING

2) SAMPLES WITH GOOD SUBJECTIVE SMOOTHNESS APPEARED MONOFIL. LIKE AT 55X.

3) TAPE SEAMS WERE USABLE IN NON-POLISHED SAMPLES AT 55X.

4) SIGNIFICANT SHEATH DISTORTION OBSERVED AROUND KNOT, BUT NO SHEATH TEARING.

5) THE MICROSTRUCTURE OF THE SHEATH FILM IS EXPANDED LIKE THE GORE PRODUCT, BUT THE TRIBOH. PRODUCT IS TO A LESSER DEGREE (550X)

6) SHEATH DISTORTION WAS EXCESSIVE IN REGIONS OF HIGH PICK DENSITY.

Discussion
- PHYS PROPS ARE LOW ESPECIALLY SINCE SHEATH INCR O.I.Am
- PET on PET/PTFE GORE BRAID SHOULD BE EXPLORED
- OVERSIZED SHEATHS DISTORT AND BECOME 'ROUGH'

Investigator [signature] Date 9/27/88
Witness [signature] Date 2-15-90

Page
Book No. 2175

Project No. MMH Experiment No. Date 10/19/88
Subject MONOFILAMENT - MULTIFILAM. HYBRID
Purpose IDEA

IDEA - FOLLOW UP FROM 2175-12.

THE ADDITION OF A SILICONE TYPE OIL TO THE TWISTED OR BRAIDED CORE BUNDLE CAN DRAMATICALLY IMPROVE PLIABILITY. HOWEVER, IT COULD ALSO INHIBIT WICKING OF BIOLOGICAL FLUID INTO THE FILAMENT CORE WHICH MIGHT OTHERWISE LEAD TO INFECTION. THIS HAS BEEN A PROBLEM WITH PREVIOUS APPROACHES OF THIS NATURE. THE LUBRICANT SHOULD BE HYDROPHOBIC (LOW SURFACE TENSION) AND COULD BE ASSORBABLE OR NONASSORBABLE. ALSO, FINE DRF FILAMENTS WOULD ALSO INHIBIT WICKING BY RESULTING IN A SMALLER DIAM. SIZE.

IF THE MONOFIL. SHEATH IS EXTRUDED, IT MAY BE BENEFICIAL TO FORM IT WITH AN ANNULAR DIE TO MINIMIZE THE PENETRATION OF THE MOLTEN SHEATH POLYMER INTO THE CORE BUNDLE. OTHER PRECAUTIONS TO MINIMIZE SHEATH-CORE ADHESION INCLUDE RAPID SHEATH QUENCHING + DRAWING/ORIENTATION.

IN THE CASE OF ASSORBABLE HYBRIDS, LOW MW ANALOGS OF PDO, CAPROLACTONE, PGA, PLA AS DESCRIBED BY AL HUNTER MAY BE USEFUL AS THE LUBRICANTS.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002624

Investigator Mah Kachik Date 10/19/88
Witness Crawford Britt Date 3-15-90

Page
Book No.
175

Project No. CBE Experiment No. Date 10/11/88
Subject Composite Braid Evaluation
Purpose Process Conditions And Props

Background: Continuation of 2175-8, 14 Composite Braids were processed and characterized - (Constructions and yarn lot info on pgs 8-11). Braid process conditions were as follows:

COMPOSITE BRAID EVALUATION
BRAID PROCESS CONDITIONS

MGS ID#	BRAIDER NO.	GEAR NO.	RPM	SHEATH SPRING DIAM. (MILS)	SHEATH SPRING LENGTH (IN)	CORE TENSION TYPE	CORE TXTRL ROD SET PT	GLASS	CORE TENSION MEAS. (GMS)
CBE-01	6	32	183	0.009		5.0 TXTRL	1.0	Y	18
CBE-02	6	32	183	0.009		5.0 TXTRL	1.5	Y	20
CBE-03	*	*	*	0.000		0.0 *	0.0	*	0
CBE-04	6	32	183	0.009		5.0 TXTRL	1.0	Y	21
CBE-05	3	36	170	0.000		0.0 TXTRL	1.0	Y	22
CBE-06	12	32	182	0.009		5.0 TXTRL	1.0	Y	20
CBE-07	12	32	182	0.009		5.0 TXTRL	1.0	Y	17
CBE-08	*	*	*	0.000		0.0	0.0		0
CBE-08A				0.000		0.0	0.0		0
CBE-09	12	32	182	0.009		5.0 TXTRL	1.0	Y	17
CBE-10	12	32	182	0.009		5.0 TXTRL	1.0	Y	19
CBE-11				0.000		0.0	0.0		0
CBE-12				0.000		0.0	0.0		0
CBE-13	10	32	183	0.009		5.0 TXTRL	1.0	Y	18
CBE-14	12	36	182	0.009		5.0 TXTRL	1.0	Y	17

Key:
TXTRL: Textrol Tension Device

MS 11/11/88

The PET/PTFE samples (CBE-01 to 05) had a range of processing problems ~~~~ such as bone-popping and looseness. CBE-03 was abandoned since the PTFE yarn was intercaled making commingling impossible. CBE-01 had springs only on PET carriers, no springs on PTFE carriers. CBE-08 (Victrex) was abandoned since commingling was impossible. CBE-12 was delayed due to sourcing problems with the bicomponent fiber.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002625

Investigator [signature] Date 11/9/88
Witness Crawford Britt Date 3-15-90

Page
Book No. 2175

Project No. CBE Experiment No. Date 11/11/88
Subject CONTINUED
Purpose

FOLLOWING BRAID PROCESSING, THE MATERIALS WERE HOT-STRETCHED ACCORDING TO THE FOLLOWING CONDITIONS:

HOT STRETCH CONDITIONS

MGS ID#	HOT-STRETCH %	ROLL 1 FPM	ROLL 2 FPM	ROLL 1 # OF WRAPS	ROLL 2 # OF WRAPS	ZONE 1 TEMP (C)	ZONE 2 TEMP (C)	ZONE 3 TEMP (C)	ZONE 4 TEMP (C)
CBE-01	30	9.0	11.7	8	12	125	150	190	225
CBE-02	30	9.0	11.7	8	12	125	150	190	225
CBE-03	0	0.0	0.0	0	0	0	0	0	0
CBE-04	30	9.0	11.7	8	12	125	150	190	225
CBE-05	30	9.0	11.7	8	12	125	150	190	225
CBE-06	10	9.0	9.8	8	12	125	150	190	215
CBE-07	10	9.0	9.8	8	12	125	150	190	215
CBE-08	0	0.0	0.0	0	0	0	0	0	0
CBE-08A	0	0.0	0.0	0	0	0	0	0	0
CBE-09	10	9.0	9.8	8	12	125	150	190	215
CBE-10	10	9.0	9.8	8	12	125	150	190	215

MS

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

INITIAL PHYSICAL PROPERTY CHARACTERIZATION YIELDED THE FOLLOWING RESULTS:

PHYSICAL PROPERTY CHARACTERIZATION

MGS ID#	USP DIAM (MILS)	ULTIMAT TENSILE STREN (LBS)	INTRIN TENSILE STREN (PSI)	ULTIMAT KNOT STREN (LBS)	INTRIN KNOT STREN (PSI)	KNOT CONVER (%)	ELONGAT (%)	STRAND BENDING RIGIDITY (GMxCM2)		KNOT STABIL (# THROWS)		PICKS PER INCH	TOTAL DENIER
CBE-01	0.0	0.00	0	0.00	0	0	0	0.00					
CBE-02	0.0	0.00	0	0.00	0	0	0	0.00					
CBE-03	0.0	0.00	0	0.00	0	0	0	0.00	0				
CBE-04	0.0	0.00	0	0.00	0	0	0	0.00					
CBE-05	0.0	0.00	0	0.00	0	0	0	0.00					
CBE-06	10.7	6.79	75450	4.37	48580	64	29	0.00	*			46	1058
CBE-07	13.9	10.16	66930	6.46	42808	64	28	0.00	*			45	1019
CBE-08	0.0	0.00	0	0.00	0	0	0	0.00					
CBE-08A	0.0	0.00	0	0.00	0	0	0	0.00					
CBE-09	14.1	15.70	100540	7.98	51490	51	29	0.00	*			44	1099
CBE-10	10.9	7.00	75030	4.47	47650	64	42	0.00	*			51	612

MS

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002626

THE PROPERTIES OF THE COMPOSITES ARE AS EXPECTED MIDWAY BETWEEN THE CONTROLS.

Investigator Mark Steckel Date 11/11/88
Witness Crawford Britt Date 3-15-90

Page 18

Book No. 2175

Project No. KAWABATA Experiment No. Date 11/15/88

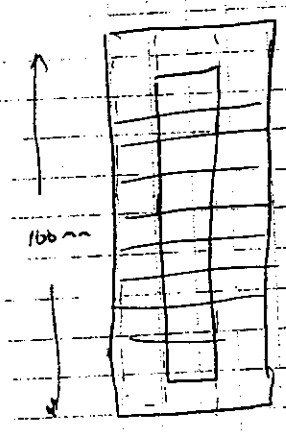
Subject KAWABATA - BENDING RIGIDITY TESTING

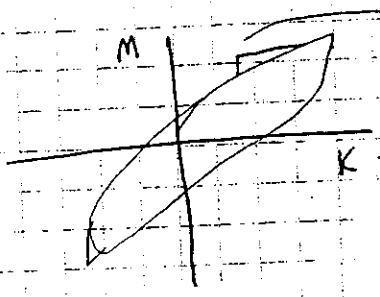
Purpose INITIAL RESULTS OF BENDING TESTING

BACKGROUND: THE KAWABATA BENDING RIGIDITY TESTER AT PHILA. COLLEGE OF TEXTILES + SCIENCE WAS UTILIZED TO MEASURE THE PLIABILITY OF BRAIDED SUTURES.

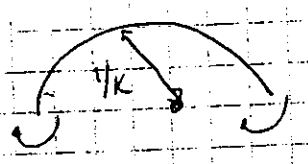
PROCEDURE:

AN ARRAY OF PARALLEL STRANDS OF BRAIDED SUTURES WERE MOUNTED BETWEEN TWO CARDBOARD TABS AS SHOWN BELOW. TYPICALLY 40 ENDS WERE USED ALTHOUGH THIS VARIES WITH THE SUTURE SIZE. THE KAWABATA TESTER MEASURES THE TORQUE AS A FUNCTION OF BENDING CURVATURE OF THE PARALLEL SUTURES. THE BENDING RIGIDITY





r = BENDING RADIUS
K = CURVATURE
M = BENDING MOMENT



CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002627

IS THE SLOPE OF THE BENDING MOMENT—CURVATURE TRACES.

THE FOLLOWING VALUES WERE OBTAINED ON OFF-BRAIDER + HOT-STRETCH POLYESTER:

BENDING RIGIDITY (GM-CM²/STRAND)	SIZE →	6-0	4-0	2-0	0	2
	OFF-BRAIDER	.004	0.026	0.029	0.036	.087
	HOT-STRETCHED	.002	0.024	0.253	0.103	0.267

AS EXPECTED, THE EI GENERALLY INCR. AS SIZE INCREASES, AND ALSO INCR. W/ HOT-STRETCHING.

Investigator [signature] Date 11/15/88

Witness [illegible] Date 2-15-90

Project No. BCAD Experiment No. Date 11/18/88
Subject BRAID CAD - MODEL CONSTRUCTIONS
Purpose DEFINE MODEL CONSTRUCTIONS

BACKGROUND: THE JOINT DEVELOPMENT PROGRAM BETWEEN ETHICON + DREXEL UNIV IS TO DEFINE SOFTWARE TO DESIGN BRAIDED SUTURES. EXPERIMENTAL DATA IS REQUIRED ON SIMPLE, WELL-BEHAVED BRAIDED GEOMETRIES IN ORDER TO CONFIRM THE THEORETICAL PREDICTIONS. THE FOLLOWING CONSTRUCTIONS HAVE BEEN CHOSEN FOR DUPONT DACRON PET TYPE 52:

CARRIERS	CORE	PICK GEARS		
3	0	22	26	30
4	0	26	30	34
8	0	28	32	36
8	1	28	34	36
12	2	28	32	36
16	3	26	30	34

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc. C.A. No.04-12457 PBS DMI002628

THE ABWE CONSTRUCTIONS ARE TO BE MADE WITH YARN WITH PRODUCER'S TWIST. TO EVALUATE THE EFFECT OF TWIST, A SMALLER SET OF SAMPLES HAS BEEN DESIGNED:

CARRIERS	CORE	PICK GEAR	TWIST LEVELS
8	1	34	0, 1.5, 3, 6

TENSILE, DIAMETER, SURFACE PROPS, BENDING RIGIDITY CHARACTERIZATION WILL BE PERFORMED ON ALL ABOVE BRAIDS.

Investigator [signature] Date 11/18/88
Witness Rosalind A. Britt Date 3-15-90

Page
Book No. 175

Project No. DUPONT Experiment No. Date 12/7/88

Subject DUPONT HOLLOW + MULTILOBAL FIBER EVALUATION

Purpose EVALUATE EXPERIMENTAL MATERIALS

BACKGROUND: TWO EXPERIMENTAL DACRON PET YARNS WERE PROVIDED BY DUPONT FOR EVALUATION AS SUTURE YARNS. YARN DESCRIPTIONS ARE GIVEN IN TABLE 1: (1) MULTILOBAL (4) HOLLOW

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002629

TABLE 1.

Exploratory Dupont Yarn

1. Dacron 50 den 34-R14
   Textile Yarn Rotoset
   Semidull Type 929 Tube
   Reference 7184 Merge 12601

2. Nylon 30 den 10-R25
   Textile Yarn Rotoset
   Dead Bright Type 335
   Reference 40244 Merge 18681

3. Nylon 70 den -66-R25-295-M
   Merge 64402

4. Polyester Hollow Multifilament Yarn
   Round Semi-dull
   71.6 den 50 filaments
   Void size : 13.8%
   Tenacity: 5.0 gpd Modulus: 90.4 gpd Elong.: 16.0%
   Finish 0.65-1.00%

THE YARNS WERE PROCESSED INTO BRAIDS ACCORDING TO MERSILENE PROCESS SPECS FOR SIMILAR DEN YARN. THE BRAIDS WERE SCOURED & HOT-STRETCHED TO MERSILENE SPECS (SEE TABLE →)

PROCESS CONDITIONS

DUPONT HOLLOW AND MULTILOBAL FIBER BRAIDS

PARAMETER	DFE-1	DFE-2
Fiber Type	Multilobal	Hollow
Denier/Filaments	50/34	72/50
Construction	16x3	12x1
Pick gear	30	12
RPM	174	174
Sheath springs	none	0.009x5"
Core tension set	1.0	1.0
Hot str %	15	15
H S Temp (F)	225	225

Investigator [signature] Date 12/7/88

Witness Ronald Brett Date 3-15-90

Project No. DuPont Experiment No. Date 12/7/88

2175

Subject CONTINUED

Purpose

RESULTS:

THE HOT-STRETCHED BRAIDS WERE CHARACTERIZED ACCORDING TO STANDARD PHYS. PROP. TESTING AND ARE COMPARED TO STANDARD MERSILENE HOT-STR. BRAIDS:

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

SUTURE PHYSICAL PROPERTIES

STANDARD AND SPECIALTY DACRON PET FIBER BRAIDS

MATERIAL DESCRIP.	DIAM (DIAM)	TENSL. STREN. (LBS)	INTRIN. TENSL. STREN. (KSI)	ELONG. (%)	KNOT STREN. (LBS)	INTRIN. KNOT STREN. (KSI)
DFE-1 MULTI-LOBAL PET 50-34-R14 SIZE 2-0	12.8	6.4	49.4	40.5	5.2	40.5
MERSILENE SIZE 2-0 GREEN	12.7	14.2	112.1	11.0	7.1	56.1
DFE-2 HOLLOW PET 72-50 SIZE 0	14.4	10.7	65.7	28.3	7.2	44.1
MERSILENE SIZE 0 GREEN	15.0	15.2	87.7	16.0	8.9	50.4

MS

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002630

DISCUSSION:

THESE YARN TYPES APPEAR TO OFFER NO SIGNIF. IMPROVEMENTS IN SUTURE PROPS. STRAIGHT + KNOT TENSILES ARE SUBSTANTIALLY LOWER IN BOTH CASES. KNOT EFFICIENCY IS RELATIVELY GOOD FOR MULTILOBAL (87% VS 50% FOR THE 2-0 CONTROL), HOWEVER IT IS NOT CLEAR WHETHER THIS IS DUE TO X-SECT SHAPE OR LOWER MODULUS YARN.

Investigator [signature] Date 12/7/88

Witness Crawford Britt Date 3-15-90

Page

Book No. 175

Project No. PDS Experiment No. Date 12/14/88

Subject PDS BRAIDS - 2 & 12 DPF EVALUATION

Purpose EVALUATE BIOLOGICAL & PHYSICAL PROPERTIES

PROCEDURE: PDS MULTIFILAMENT YARNS WERE BRAIDED AND EVALUATED FOR BIOLOGICAL PROPERTIES AND (IN VITRO AND INVIVO). THE YARN WAS OBTAINED FROM DR. E. BROYER AND POSSESSED THE FOLLOWING PROPS:

Properties of PDS* Yarns

sample	denier	dpf	tenacity g/den	elong. %
RLS-248E	58.7	11.74	6.75	63
QPY-022-3-2	74.9	14.98	4.8	21 MS
QPY-023-5-1	67.3	13.46	5.6	21
PY-045	57.8	2.06	5.25	59.95

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

ALL YARN WAS BRAIDED PER VICRYL 2-0 SPECIFICATION THE FOLLOWING COMPARES THE INVIVO AND INVITRO DATA VS. PDS MONOFILAMENT AND VICRYL BRAID:

PDS BRAID IN VITRO PERFORMANCE

BRAID ID	FIBER DPF	YARN ID	BRAID SIZE	BASELINE TENSILE (PSI)	IN VITRO 5 DAY % BSR	PDS MONOFIL TENSILE (PSI)	PDS MONOFIL IN VITRO 5D %BSR	VICRYL BRAID TENSILE (PSI)	VICRYL BRAID IN VITRO 12D %BSR	INVIVO 21 DAY % BSR
CBS-001	2.1	PY-045	2-0	70930	23.6	87490	64.2	112300	54.8	3
CBS-002	15.0	QPY-022	2-0	57300	34.9	87490	64.2	112300	54.8	22
CBS-003	11.7	RLS-248E	2-0	70270	47.1	87490	64.2	112300	54.8	26
CBS-004	13.5	QPY-023	3-0	61350	48.7	95440	82.1	120150	56.2	36 MS

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002631

Discussion:

THE 2 DPF PRODUCT HAS EXCEPTIONALLY POOR BSR - 3%. AT 21 DAY VS APPROX 50% FOR VICRYL 2-0. THE ~12 DPF PRODUCT WERE SIGNIFICANTLY BETTER BUT STILL INFERIOR TO VICRYL OR PDS MONOFIL. THE HAND OF THE PRODUCT WAS ALSO INFERIOR TO VICRYL FROM A STIFFNESS VIEWPOINT. THE 2-0 DPF POSSESSED A HIGH # OF BROKEN FILAMENTS WHICH CONTRIBUTED TO BRAID ROUGHNESS.

Investigator [signature] Date 12/14/88

Witness Priscilla Britt Date 3-15-90

Page
Book No.

Project No. IFI Experiment No. Date 12/14/88

Subject BRAID PROCESS CONDITIONS, H.S. CONDITIONS, PHYS PROP CHARACT. 2175

Purpose CHARACTERIZATION OF COMPOSITE IFI BRAIDS

CONTINUATION FROM P6. 6:

BACKGROUND: ROOT AND RMS VICRYL/PDS + PET/PP BRAID CONSTRUCTIONS HAVE BEEN DEFINED PREVIOUSLY. BRAIDS WERE PROCESSED ACCORDING TO FOLLOWING CONDITIONS:

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

IFI BRAID PROCESS CONDITIONS

IFI #	LAB ID #	SIZE	TYPE	FIBER 1	FIBER 2	PICK GEAR #	SHEATH SPRING DIAM.x LENGTH	CORE TENS TYPE	CORE TENS SET	CORE TENS MEAS (GMS)	BRAIDER RPM	PLY TWIST (TPI)
1	SBZ-020	4-0	ROOT	VIC	PDS	27	NONE	TXTL	0.0	12	160	*
2	SBZ-007	4-0	ROOT	VIC	PDS	20	NONE	BUTT	NONE		180	*
3	SBZ-009	4-0	ROOT	PET	PP	29	NONE	NONE	*	*	180	*
4	SBZ-005	3-0	ROOT	VIC	PDS	30	9x5.0	NONE	*	*	160	*
5	SBZ-006	3-0	ROOT	VIC	PDS	30	9x5.0	NONE	*		180	*
6	SBX-010	3-0	ROOT	PET	PP	30	9x5.0	BUTT	9x5.0		183	*
7	SBZ-023	3-0	RMF	PET	PP	31	9x5.0	TXTL			160	3.0
8	SBZ-022	3-0	RMF	PET	PP	30	9x5.0	TXTL	0	20	182	3.0
9	SBZ-021	3-0	RMF	VIC	PDS	27	9x5.0	TXTL		12	182	3.0
10	SBZ-025	3-0	RMF	PET	PP	31	NONE	TXTL		35	160	3.0
11	SBZ-024	3-0	RMF	VIC	PDS	31	9x5.0	TXTL			183	3.0
12	SBZ-028	3-0	RMF	VIC	PDS	--	--	----	----	---	0	---
13	SBZ-027	3-0	RMF	PET	PP	31	NONE	TXTL		26	160	3.0
14	*	3-0	RMF	VIC	PDS	*	*	*	*	*	0	*
15	SBZ-013	4-0	ROOT	PET	PP	27	NONE	BUTT		80	182	3.0

CORE COPPING WAS A CONSIDERABLE PROBLEM IN NEARLY ALL BRAIDS DUE TO MISMATCH'S IN ELASTIC MODULI.

ALL MATERIALS WOUND ON HALOBA AND BRAIDED ON W.E. BUTTS. TEXTMA TENSION CONTROL UNITS WERE USED ON CORE YARNS.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002632

Investigator [signature] Date 12/14/88

Witness Crawford Britt Date 3-15-90

Page 03

Book No. 175

Project No. IFI Experiment No. Date 12/14/88

Subject

Purpose CONTINUED

AFTER BRAIDING AND APPROPRIATE SCOURING (ETAC FOR VIC/PDS, AQUEOUS DETERGENT FOR PP/PET), THE BRAIDS WERE HOT-STRETCHED IN A FORCED CONVECTION TUNNEL AT THE FOLLOWING CONDITIONS:

IFI BRAID HOT-STRETCH CONDITIONS

IFI #	LAB ID#	FIBER 1	FIBER 2	HOT-STRET PERCN (%)	GODET 1 FPM	GODET 1 # WRPS	GODET 2 # WRPS	ZONE 1 TEMP (F)	ZONE 2 TEMP (F)	ZONE 3 TEMP (F)	ZONE 4 TEMP (F)
1	SBZ-020	VIC	PDS	*	0.0	0	0.0	0	0	0	0
2	SBZ-007	VIC	PDS	22	9.0	9	11.0	125	150	175	195
3	SBZ-009	PET	PP	35	7.0	7	10.7	122	146	170	194
4	SBZ-005	VIC	PDS	11	9.0	7	10.0	122	146	170	194
5	SBZ-006	VIC	PDS	22	9.0	7	11.0	125	150	175	195
6	SBX-010	PET	PP	34	8.0	7	10.7	175	225	250	300
7	SBZ-023	PET	PP	34	8.0	8	10.7	175	225	250	300
8	SBZ-022	PET	PP	34	8.0	7	10.7	175	225	250	295
9	SBZ-021	VIC	PDS	10	10.0	7	11.0	125	150	175	195
10	SBZ-025	PET	PP	34	8.0	7	10.7	175	225	250	295
11	SBZ-024	VIC	PDS	34	8.0	9	10.0	125	150	175	195
12	SBZ-028	VIC	PDS	--	0.0	0	0.0	0	0	0	0
13	SBZ-027	PET	PP	--	0.0	0	0.0	0	0	0	0
14	*	VIC	PDS	*	0.0	0	0.0	0	0	0	0
15	SBZ-013	PET	PP	34	8.0	7	10.7	175	225	250	300

MB

A HIGHER THAN PREFERRED HOT-STRETCH RATIO WAS SOMETIMES REQUIRED IN ORDER TO REMOVE THE WIDE-SPREAD BONE-POPS.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002633

Investigator [signature] Date 12/14/88

Witness Crawford Britt Date 3-15-90

Project No. IFI Experiment No. Date 12/17/88

Subject

Purpose CONT...

THE FOLLOWING ARE THE PHYSICAL PROPERTIES OF THE IFI BRAIDS. ~~THE BRAIDS~~

IFI BRAID COMPOSITES TEST RESULTS

IFI #	TYPE FIBER 1	FIBER 2	SIZE	DIAM (MILS)	STD. DEV.	TENSL (LBS)	STD. DEV.	INTRIN TENSL (PSI)	KNOT TENSL (LBS)	STD. DEV.	INTRIN KNOT TENSL (PSI)	ELONG (%)	STD. DEV.
2	ROOT VIC	PDS	4-0	8.9	0.1	5.5	0.2	87.8	3.6	0.3	57.7	25.7	1.3
3	ROOT PET	PP	4-0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
4	ROOT VIC	PDS	3-0	10.3	0.0	7.8	0.4	93.7	4.8	0.2	57.9	29.2	2.2
5	ROOT VIC	PDS	3-0	10.4	0.2	6.6	0.1	0.0	4.2	0.5	0.0	16.9	1.2
6	ROOT PET	PP	3-0	10.9	0.0	6.1	0.2	65.8	4.4	0.2	47.5	28.2	3.1
7	RMF PET	PP	3-0	11.6	0.2	6.7	0.1	0.0	4.7	0.2	0.0	31.8	1.5
8	RMF PET	PP	3-0	12.9	0.1	7.9	0.1	0.0	5.4	0.2	0.0	24.1	1.0
9	RMF VIC	PDS	3-0	11.0	0.1	8.3	0.2	0.0	4.4	0.2	0.0	34.0	1.6
10	RMF PET	PP	3-0	12.7	0.1	7.5	0.1	0.0	5.0	0.3	0.0	22.4	0.7
11	RMF VIC	PDS	3-0	10.5	0.2	7.5	0.1	0.0	5.0	0.3	0.0	21.0	0.6
12	RMF VIC	PDS	3-0	12.6	0.1	11.2	0.2	0.0	6.4	0.2	0.0	28.2	1.2
13	RMF PET	PP	3-0	7.8	0.1	4.1	0.1	0.0	2.6	0.1	0.0	12.4	1.2
14	RMF VIC	PDS	3-0	******	****	*****	****	******	*****	****	******	*****	****
15	ROOT PET	PP	4-0	10.2	0.1	7.8	0.4	91.7	4.3	0.2	52.8	29.2	2.2
1	ROOT VIC	PDS	4-0	7.9	0.1	4.5	0.2	92.3	2.8	0.1	58.2	29.3	2.0

MS

APPROXIMATELY 750 YDS OF EACH BRAID WAS DELIVERED TO DR. E. BROWN FOR FURTHER PROCESSING.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002634

Investigator Date 12/14/88

Witness Crawford Britt Date 3-15-90

Page
Book No.
175

Project No. CBE Experiment No. Date 2/2/89
Subject PET/PTFE COMPOSITE BRAIDS
Purpose EXPLORATORY EVALUATION OF VARIOUS PROCESS METHODOLOGIES

BACKGROUND - PAGE 8

ADDITIONAL PET/PTFE COMPOSITES BRAIDS WERE PRODUCED UTILIZING 1) CARRIER BLEND, 2) YARN BLEND, 3) COMMINGLING TECHNOLOGIES. CONTROLS OF 100% PET AND 100% PTFE WERE ALSO PRODUCED. FIBER SUPPLY / TYPE / DENIER, BRAID CONSTRUCTION, SLEEVE CONDITION, H.S. CONDITIONS WERE CONSTANT FOR ALL BRAIDS.

THE FOLLOWING IS THE YARN INFORMATION / DESCRIPTION:

COMPOSITE BRAID EVALUATION
YARN A DESCRIPTION

MGS ID#	FIBER A	FIB A DENIER	FIB A FILAM COUNT	FIB A SOURCE	FIB A LOT #	FIB A COLOR	FIB A TWIST LEVEL (TPI)	FIB A TWIST DIRCT (S/Z)	FIB A ENTANG LEVEL
CBE-15	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-16	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-16A	PET	70	34	DUPONT		WHIT	0.0 *		R14
CBE-17	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-18	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0
CBE-19	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *		0

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

COMPOSITE BRAID EVALUATION
YARN B DESCRIPTION

MGS ID#	FIBER B	FIB B DENIER	FIB B FILAM COUNT	FIB B SOURCE	FIB B LOT #	FIB B COLOR	FIB B TWIST LEVEL (TPI)	FIB B TWIST DIRCT (S/Z)	FIB B ENTNG LEVEL
CBE-15	PTFE	110	15	DUPONT	1T138	WHIT	0.0 *		0
CBE-16	PTFE	110	15	DUPONT	1T138	WHIT	0.0 *		0
CBE-16A	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *		0
CBE-17	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *		0
CBE-18	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *		0
CBE-19	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *		0

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002635

Investigator [signature] Date 2/2/89
Witness [illegible] Britt Date 3-15-90

Page 61
Book No. 2175

Project No. CBE Experiment No. Date 2/2/89
Subject PET/PTFE Composites
Purpose Contin

APPROX. 50/50 BY VOLUME BRAIDS WERE PRODUCED IN THE FOLLOWING CONSTRUCTION + CONDITIONS:

COMPOSITE BRAID EVALUATION
BRAID CONSTRUCTIONS

MGS ID#	COMP TYPE	BRAID TYPE	SIZE	SHxCR CARR.	FIBER A	DEN A	FIBER A VOLUM FRACT	FIBER B	DEN B	FIBER B VOLUMN FRACT	SH CARR FIB A	SH CARR FIB B	SH CARR FIB C	CR CARR FIB A	CR CARR FIB B
CBE-15	CB	CS	1	12x1	PET	70	51	PTFE	110	49	DIAGRM	DIAGRM	*	1	1
CBE-16	YB	CS	1	12x1	PET	70	51	PTFE	110	49	1-12	1-12	*	1	1
CBE-16A	YB	CS	1	12x1	PET	70	51	PTFE	115	49	1-12	1-12	*	1	1
CBE-17	CF	CS	1	12x1	PET	70	51	PTFE	115	49	1-12	1-12	*	1	1
CBE-18	CT	CS	1	12x1	PET	70	100	PTFE	115	*	1-12	*	*	1	*
CBE-19	CT	CS	2	12x1	PET	70	*	PTFE	115	100	*	1-12	*	*	1

COMPOSITE BRAID EVALUATION
BRAID PROCESS CONDITIONS

MGS ID#	BRAIDER NO.	GEAR NO.	RPM	SHEATH SPRING DIAM. (MILS)	SHEATH SPRING LENGTH (IN)	CORE TENSION TYPE	CORE TXTRL SET	GLASS ROD PT	CORE TENSION MEAS. (GMS)
CBE-15	12	30	182	0.009	5.0	TXTRL	1.0	Y	16
CBE-16	00	31	215	0.009	5.0	TXTRL	1.0	Y	16
CBE-16A	00	36	215	0.009	5.0	TXTRL	1.0	Y	20
CBE-17	12	32	182	0.009	5.0	TXTRL	0.0	Y	14
CBE-18	12	30	182	0.009	5.0	TXTRL	1.0	Y	17
CBE-19	12	36	182	0.009	5.0	TXTRL	1.0	Y	15

Investigator [signature] Date 2/2/89
Witness Crawford Britt Date 3-15-90

Page
Book No. 2175

Project No. CBE Experiment No. Date 2/2/89

Subject CET / PTFE COMPOSITES

Purpose CONTINUED

THE ABOVE BRAIDS WERE SCOURED IN SKEIN FORM IN A BEAKER W/ AN AQUEOUS DETERGENT SYSTEM. FOLLOWING SCOURING ONLY, THE BRAIDS WERE HOT-STRETCHED AS FOLLOWS:

COMPOSITE BRAID EVALUATION
HOT STRETCH CONDITIONS

MGS ID#	HOT-STRETCH %	ROLL 1 FPM	ROLL 2 FPM	ROLL 1 # OF WRAPS	ROLL 2 # OF WRAPS	ZONE 1 TEMP (C)	ZONE 2 TEMP (C)	ZONE 3 TEMP (C)	ZONE 4 TEMP (C)
CBE-15	30	9.0	11.7	8	12	125	150	190	225
CBE-16	30	9.0	11.7	8	12	125	150	190	225
CBE-16A	30	9.0	11.7	8	12	125	150	190	225
CBE-17	30	9.0	11.7	8	12	125	150	190	225
CBE-18	30	9.0	11.7	8	12	125	150	190	225
CBE-19	30	9.0	11.7	8	12	125	150	190	225

THE HOT-STRETCHED BRAIDS WERE CHARACTERIZED PER STANDARD SUTURE TEST METHODS:

COMPOSITE BRAID EVALUATION
PHYSICAL PROPERTY CHARACTERIZATION

MGS ID#	USP DIAM (MILS)	ULTIMAT TENSILE STREN (LBS)	INTRIN ULTIMAT TENSILE STREN (PSI)	KNOT ULTIMAT TENSILE STREN (LBS)	KNOT INTRIN TENSILE STREN (PSI)	KNOT CONVER (%)	ELONGAT (%)	BENDING RIGIDITY (GMxCM2)	KNOT STABIL (# THROWS)	BSR CONTL (LBS)	21 DAY (LBS)	21 DAY BSR (%)	PICKS PER INCH	TOTAL DENIER
CBE-15	18.6	14.14	51758	9.64	35254	68	34	2.24E-2	5	0.00	0.00		44	2529
CBE-16	19.1	13.07	45460	9.52	33116	73	30	2.20E-2	5	0.00	0.00		45	2694
CBE-16A	0.0	0.00	0	0.00	0	0	0	0.00		0.00	0.00		41	2565
CBE-17	19.9	13.88	44850	11.02	35600	79	39	1.28E-2	5	0.00	0.00			
CBE-18	19.5	21.30	71295	13.54	45241	63	27	3.00E-2	4	0.00	0.00			
CBE-19	20.6	7.37	21460	5.96	17763	79	57	1.12E-2	7	0.00	0.00		39	2970

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002637

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

Investigator Date 2/2/89

Witness Crawford Britt Date 3-15-90

Page
Book No. 2175

Project No. CBE Experiment No. Date 2/2/89

Subject PET/PTFE COMPOSITES

Purpose CONTINUED:

(1) DISCUSSION:

FROM A BRAID PROCESSING VIEWPOINT, THE COMMINGLED YARN WAS THE LEAST PROBLEMATIC BRAID FOLLOWED BY THE YARN BLEND. THE CARRIER BLEND PRESENTED THE MOST DIFFICULTIES IN CORE LOADING AND BRAID LOOSENESS. THE COMMINGLED YARN DID POSSESS REGIONS WHERE THE YARNS SEPARATED RESULTING IN BRAIDING DIFFICULTY AND ROUGHNESS.

FROM A PROPERTY VIEWPOINT, THE INTRINSIC TENSILES OF THE THREE COMPOSITES WERE CLOSE AND APPROXIMATED A RULE OF MIXTURES AVERAGE OF THE TWO CONTROL BRAIDS. THE CARRIER BLEND WAS APPROX 10% HIGHER. INTRINSIC KNOT STRENGTHS WERE VERY SIMILAR AMONG THE COMPOSITES AND WERE 75-80% OF THE PET CONTROL KNOT STRENGTH. THE COMM. HAD THE HIGHEST KNOT CONVERSION (79%). THE BENDING RIGIDITY OF THE COMMINGLED WAS HALF THE OTHER TWO COMPOSITES, PERHAPS REFLECTING THE MORE HOMOGENEOUS MIXTURE OF THE TWO COMPONENTS. ALL 3 COMPOSITES HAD KNOT SECURITYS OF 5 THROWS - SIGNIFICANTLY BETTER THAN 7 FOR 100% PTFE.

CONFIDENTIAL - NON-PATENT - PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002638

Investigator [signature] Date 2/2/89

Witness Crawford Britt Date 3-15-90

Page
Book No. 175

Project No. CBE Experiment No. Date 3/6/89

Subject VICRYL/PDS BRAID COMPOSITE

Purpose IN-VIVO DATA

BACKGROUND:

THE VICRYL/PDS COMPOSITE BRAIDS DESCRIBED BY PDS 10-11 WERE TESTED FOR IN-VITRO PROPERTIES.

THE FOLLOWING RESULTS WERE OBTAINED BY ERF (89-064):

SAMPLE	SIZE	0 DAY BASELINE (LBS)	21 DAY (LBS)	(%)
CBE-6	2-0	6.65	2.43	36.5
CBE-7	2-0	9.45	4.07	43.1
CBE-9	2-0	14.51	7.03	48.5
CBE-10	2-0	6.51	1.86	28.6

DISCUSSION

CBE-6 IS A CARRIER BLEND, CBE-7 IS YARN BLEND, CBE-9 IS VICRYL CONTROL AND CBE-10 IS PDS CONTROL. THE VICRYL CONTROL IS CLOSE TO PROLENE AVES. THE 2 COMPOSITES FALL BETWEEN THE 2 CONTROLS AS EXPECTED, HOWEVER THE YARN BLEND RETAINED MORE STRENGTH AND WAS STRONGER TO START. THIS IS PROB BUT TRUE TO DIFFERENCES IN EXPOSURE HISTORY.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002639

Investigator [signature] Date 3/6/89

Witness Crawford Britt Date 3-15-90

Project No. STU Experiment No. Date 4/1/89

Subject SURFACE TREATMENT VICRYL

Purpose IDEA DOCUMENTATION

A SURFACE TREATMENT, SUCH AS PLASMA FLUORINATION WHICH LOWER THE SURFACE ENERGY OF AN ABSORBABLE SUTURE, MAY IMPROVE THE SUTURE'S BSR DUE TO INHIBITED WETTING OF THE SURFACE BY H_2O. IT IS SPECULATED THAT H_2O MUST FIRST BE ADSORBED ONTO THE POLYMER SURFACE BEFORE HYDROLYSIS (RESULTING IN CHAIN SCISSION AND STRENGTH DEGRADATION) CAN OCCUR SO THAT SLOWING THE ADSORPTION STEP BY MAKING IT MORE HYDROPHOBIC SHOULD SLOW THE TENSILE LOSS. ADDITIONAL PRODUCT IMPROVEMENTS MAY INCLUDE INCREASED PLIABILITY DUE TO INCREASED FIBER LUBRICITY AS WELL AS IMPROVED KNOT TIE-DOWN.

THE PROCESS WOULD PREFERABLY BE CONTINUOUS. FLUORINE ATOMS WOULD BE GRAFTED ONTO THE POLYMER BACKBONE, THE DEGREE DETERMINED BY THE RESIDENCE TIME AND CONCENTRATION OF THE PLASMA.

Investigator [signature] Date

Witness Crawford Britt Date 3-15-90

Page
Book No. 2175

Project No. EI Experiment No. Date 5/23/89
Subject KAWABATA BENDING RIGIDITY CHARACT
Purpose EVALUATE ETHIBOND STANDARD - EXTRA, TICRON

BACKGROUND:
THE BENDING RIGIDITY OF SIZE 2 ETHIBOND, ETH. EXTRA, AND Ti-CRON (10+0) WERE DETERMINED USING THE KAWABATA PURE BENDING TESTER AT P.C.T., U.S.. SIX SAMPLES OF EACH WITH 36 STRANDS PER SAMPLE WERE TESTED (216 TOTAL) AS DESCRIBED ON PG 18.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

RESULTS:

DESCRIP	SUTURE EI (gm·cm²/STRAND)	STD DEV
ETHIBOND/PRODUCTION/NON-STERIL	3.64 E-2	0.24 E-2
ETHIBOND/PRODUCTION/Co 60	3.64 E-2	0.32 E-2
ETHIBOND EXTRA/NON-STERIL	2.16 E-2	0.22 E-2
Ti-CRON/SILICONE/STERIL*	5.28 E-2	0.42 E-2

* HAND STRETCHED TO MINIMIZE MEMORY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002641

ANALYSIS
THE DATA SUGGESTS: 1) SIGNIFICANTLY LOWER EI OR "IMPROVED PLIABILITY" FOR ETHIBOND EXTRA, 2) NO SIGNIFICANT EFFECTS OF Co 60 STERIL. ON PRODUCTION ETHIBOND EI, AND 3) LOWER EI OR HIGHER PLIABILITY OF CURRENT ETHIBOND VS TICRON. HOWEVER, IT SHOULD BE NOTED THAT THE BRAID M-K CURVES ARE NON-LINEAR SO THAT THE EI IS DEPENDENT ON WHERE THE SLOPE IS TAKEN. THE ABOVE DATA IS THE TIGHTER REGION OF CURVATURE (K=1.5 TO 2.5 cm⁻¹). IT SHOULD BE NOTED AT LOWER VALUES OF K THAT TICRON IS MORE PLIABLE THAN ETHIBOND STANDARD, BUT THAT ETHIBOND EXTRA EXHIBITS THE LOWEST EI OVER THE ENTIRE RANGE OF CURVATURES.

Investigator [signature] Date 5/23/89
Witness Donald Britt Date 3-15-90